

Application No. 10/737,324

REMARKS

Currently, claims 1-6, 8-23 and 29-34 are pending in the application, claims 7 and 24-28 being withdrawn as a result of a restriction requirement and election of species.

Claims 1, 29, 33 and 34 are amended with basis at, for example, Figure 2 and page 4, lines 19-20.

I. APPLICANTS' INVENTION

The present invention relates to removable device such as a stent-graft, intended for applications where it may be desirable to remove the device at some time following implantation. The stent-graft includes a helically-wound stent component provided with a covering of graft material. It is removable by gripping an end of the helically-wound stent component with a retrieval device and applying tension to the stent component in the direction in which it is intended to be withdrawn from the site of implantation. The use of such a retrieval device allows the stent-graft to be removed remotely, such as via a catheter inserted into the body at a different location from the implantation site. The design of the stent-graft is such that the stent component is extended axially while the adjacent portion of the graft separates between windings of the stent component. The axial extension of the stent component, with portions of the graft still joined to the stent component, allows the device to be "unraveled" (or "unwound") and removed through a catheter of diameter adequately small to be inserted into the body cavity that contained the stent-graft. It is removed atraumatically, without incurring significant trauma to the body conduit in which it had been deployed.

II. CLAIM OBJECTIONS

Claim 20 is canceled herein in response to the objection.

III. REJECTION OF CLAIM 34 UNDER 35 USC 102(b) AS ANTICIPATED BY SCHWARTZ et al., US PATENT 5,799,384.

Schwartz et al. teach the construction of a stent-graft made from a length of serpentine wire having a length of a "flexible film" material joined to the length of the wire, with the wire more or less centered between the edges of the strip of flexible film. The wire and attached strip of flexible film are helically wound (by wrapping around a mandrel that is subsequently removed) to create the tubular stent-graft. The adjacent edges of adjacent helical windings of the flexible film are specified as not being bonded or otherwise sealed together.

Application No. 10/737,324

The Examiner is of the opinion that, because the adjacent edges of the graft material of the Schwartz et al. device are not attached to each other, that the graft material of that device is capable of being split (defined by the Examiner as "separated").

Applicants respectfully disagree with the Examiner's position. First (as recognized by the Examiner), Schwartz et al. do not teach or suggest removability of their device following implantation. Second, Schwartz et al. does not teach or suggest splittability as taught by the present application. If the helical windings are never joined to form a substantially continuous luminal surface and thus remain separate and discrete "layers," they cannot be said to be "splittable" as presently claimed.

The "splittable" character of the present invention is described at page 4, lines 16-20, page 11, lines 1-18 and (for example) by Figure 2. The Examiner states that the term "splittable" is not defined explicitly and notes that while claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Applicants' position is that the "splittable" limitation is suitably defined and that no additional specification limitation is being read into the claim. As noted previously, the helical windings with their attached tape of film taught by Schwartz et al. are not joined and are separate and discrete. As such, they do not meet the requirement of the present amended claim for a graft covering that "...covers spaces between adjacent elements of the stent component in a substantially integral and continuous fashion..." Accordingly, the present claim is not anticipated by the graft covering taught by Schwartz et al.

IV. REJECTION OF CLAIMS 1-6, 8-10, 12-15, 17-20, 22 AND 33 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 IN VIEW OF BOSLEY, JR., US PATENT 5,514,176.

Please note that claim 20 is now canceled.

Schwartz et al. is described above. Bosley, Jr. teaches the construction of a removable stent-graft in the form of a helically wound non-serpentine coil (which may be made of a variety of materials including wire) provided with a covering (preferably an outer covering) of a material such as silicone that secures adjacent coil loops together. The adjacent coil loops are specified to be in abutting relationship (see, for example, the first paragraph of the Summary of the Invention at col. 2, lines 40-53 and all figures; also please note the second sentence of the Abstract and the first sentence of the Detailed Description at col. 4, lines 10-11).

The Examiner states that Schwartz et al. discloses an endoprosthesis with all the elements of claims 1 and 33, but adds that Schwartz et al. is silent as to removability of the endoprosthesis by cohesive disassembly.

Application No. 10/737,324

The present claims require that the graft material is substantially integral and continuous between adjacent elements of the stent component. Clearly Schwartz et al. teach that their graft covering, in the form of a film tape attached to the helically wound wire, is discontinuous between adjacent stent windings (e.g., see col. 5, lines 1-5 where it is stated that "It will also be appreciated by those skilled in the art that the discontinuity of the film 8 between adjacent windings 14 provides means for relieving longitudinal strain on the stent as it is expanded in a body lumen."). Bosley, Jr. teaches a continuous silicone covering over a helical stent winding that requires that adjacent windings are in direct contact with each other, i.e., there cannot be spaces between adjacent windings. While both of these references teach stent devices, the discontinuous character of the device of Schwartz et al. is entirely contrary to the requirement of the continuous covering of Bosley Jr. and the requirement for the adjacent stent windings of Bosley Jr. to be in direct contact. As such, these are not combinable without destroying essential features of the other.

As such, the present invention is not obvious over the combination of Schwartz et al. and Bosley, Jr.; these references have opposing requirements that prevent their combination; even if they were considered to be combinable they offer no reason to combine without benefit of hindsight based on the present specification.

V. REJECTION OF CLAIMS 11, 16 AND 21 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 AND BOSLEY, JR., US PATENT 5,514,176 AS APPLIED TO CLAIMS 1 AND 20 ABOVE, AND FURTHER IN VIEW OF SMITH, US PATENT 6,364,904.

Smith teaches the construction of a stent-graft from materials that include ePTFE, which is known to be permeable. Claims 11, 16 and 21 relate to permeability of the graft material and the use of ePTFE as the graft material. As described above, the present claims are patentable over Schwartz et al. and Bosley, Jr. for the same reasons described above for claims 1, 33 and 34.

VI. REJECTION OF CLAIM 23 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 AND BOSLEY, JR., US PATENT 5,514,176 AS APPLIED TO CLAIMS 22 ABOVE, AND FURTHER IN VIEW OF BIGUS et al., US PATENT 6,629,992.

The Examiner describes that Schwartz et al. describes means for splitting being a cut and that Bigus et al. teach an endoprosthesis wherein a sheath is provided with perforations as an alternative to a cut to provide the sheath with a weakened area at a desired location. He concludes that it would have been obvious to look to the teachings of Bigus et al. in order to provide perforations as a means of providing a weakened area that would split.

First, the cuts of Schwartz et al. are not intended to provide for splitting of the graft material but rather to provide flexibility to the serpentine wire from which the stent is wound and strain relief to the graft material in order to accommodate the change in diameter of the stent-graft during

Application No. 10/737,324

balloon expansion. These cuts are provided during manufacture of the stent-graft. There is no suggestion that they are present to allow for splitting or tearing of the graft material during removal of the graft by unwinding or unraveling. Indeed, as noted above, Schwartz et al. do not suggest graft removal by any means including unwinding.

Likewise, the perforations taught by Bigus et al. are longitudinally oriented and intended to allow for splitting of a sheath that constrains a self-expanding endoprosthesis prior to deployment to a larger diameter. The splitting of the sheath to initiate deployment releases the constrained stent allows it to self-expand.

It is clear that the sheath is not intended as a functional part of the endoprosthesis, but rather only as a component provided for stent delivery and deployment. As such, this teaching is not suggestive of a splittable graft material that is part of the stent-graft. The entirely different orientation of the splittable material is also not suggestive of the helical orientation of the perforations necessary to allow for removal of the present stent-graft. These differences are such that the person of skill would be extremely unlikely to look to Bigus et al. for teachings related to the construction of a stent-graft including a graft material that forms a continuous luminal surface that may be cohesively dissembled to allow its removal, as by tearing or splitting of the graft material between adjacent elements of the stent component.

VII. REJECTION OF CLAIMS 29 AND 31 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 IN VIEW OF CULLY et al., WO00/42949.

Claim 29 requires that the raised apex, covered by the graft material, is located between the ends of the stent.

Schwartz et al., as described above, teach the construction of a stent-graft from a length of serpentine wire to which is affixed a strip of flexible film. The serpentine wire with attached strip of film is subsequently wrapped into a helical form wherein adjacent edges of the film of adjacent helical windings are not sealed together, resulting in a discontinuous luminal surface. Cully et al. teach a stent-graft with a continuous luminal surface that includes a length of helically wound serpentine wire as the stent component. Some apices located between the ends of the stent-graft are raised to serve as in vivo tissue anchors. The raised apices of Culley et al. are not covered by the graft material; rather they remain open and allow tissue to grow into the open loop formed by the raised wire apex.

The Examiner concludes that, given the raised apex teaching of Cully et al., it would be obvious to raise at least one apex of the helically wound serpentine wire of Schultz et al. to form an anchor provided with covering of the attached graft material.

There are several difficulties with this conclusion. First, Cully et al. teach the construction of a biliary stent-graft intended to be impermeable at relatively high pressures (see Culley et al. at

Application No. 10/737,324

page 2, line 33 to page 3, line 23). Schwartz et al., in teaching away from the sealing of adjacent windings, cannot serve in any pressure-resistant application that would allow leakage through the wall of the device as would happen between adjacent windings of the graft of Schwartz et al. with its discontinuous luminal surface. Thus anyone considering the teaching of Schwartz et al. for a stent-graft would not be considering the biliary graft teachings of Cully et al.

Further, both references teach the construction of a tubular device wherein the luminal and exterior surfaces of the graft material form relatively smooth luminal and exterior surfaces (continuous or discontinuous) with, in the case of the Culley et al. reference, the occasional raised wire apex extending above the graft material. There is no suggestion in either reference to provide the covering over a raised apex that would disrupt the tubular shape of the graft material. It is simply counter-intuitive to do this and is not taught or suggested in either reference.

VIII. REJECTION OF CLAIMS 30 AND 32 UNDER 37 CFR 103(a) AS UNPATENTABLE OVER SCHWARTZ et al., US PATENT 5,799,384 AND CULLY et al., WO00/42949 AS APPLIED TO CLAIMS 29 AND 31 ABOVE, AND FURTHER IN VIEW OF BOSLEY, JR., US PATENT 5,514,176.

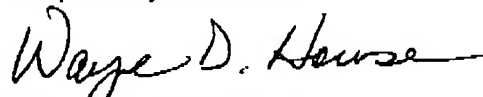
These claims depend respectively from claims 29 and 31 as argued above. Their language is the same, each requiring that the endoprosthesis is adapted to be cohesively disassembled to allow for removal. Thus the arguments presented above pertaining to claims 29 and 31 apply here. Likewise, the previous arguments directed to cohesive removal apply here as well. Finally, Culley et al. do not teach or suggest removability. Ultimately, these references in combination do not teach removability of a stent graft with spaces between adjacent elements of the generally helically wound wire covered by a graft material that forms a continuous luminal surface and is adapted for cohesive disassembly to allow for removal of the endoprosthesis from a patient.

Application No. 10/737,324

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance. If there remain any issues that might benefit from further discussion, the Examiner is requested to telephone the undersigned practitioner; likewise, the Applicants request an interview if such issues may remain.

Respectfully Submitted,



Wayne D. House 34,623
W. L. Gore & Associates, Inc.
551 Paper Mill Road
P.O. Box 9206
Newark, DE 19714-9206
(928) 864-2574

Date: 26 APRIL 2006